The Committee for Conformity Assessment of Accreditation and Certification on Functional and Technical Textiles
Specified requirements of protective clothing for surgical gown
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1.Scope：

This standard gives general guidance on the characteristics of surgical gown used as medical device for clinical staff. It is intended to prevent the transmission of infective agents between patients and clinical staff during surgical and other invasive procedures. Surgical mask, surgical gloves, foot and head wear are not covered by this standard.

2.Terminology：

2.1 surgical gown：gown worn by member of a surgical team to prevent transfer of infective agents.

2.2 critical product area：product area with a greater probability to be involved in the transfer of infective agents to or from the wound, e.g. front and sleeves of surgical gowns.

2.3 resistance to microbial penetration：ability of material(s) to withstand penetration of micro-organisms from one side through to the other.

2.4 dry penetration：effect of a combination of air movement and mechanical action by vibration on microbial penetration in dry condition.

2.5 wet penetration：effect of combination of wetness, pressure and rubbing on microbial penetration.

2.6 colony forming unit（CFU）：unit by which the culturable number of microorganisms is expressed.

2.7 barrier index (BI)：describes the fraction of the microbial challenge which has not penetrated the barrier material. BI increases as barrier performance increases.

3. Requirements：

class characteristic	Unit	High performance		Standard performance	
		Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration－Dry	Log_{10} (CFU)	—	≤2 [a]	—	≤2 [a]
Resistance to microbial penetration－Wet	BI	6.0 [b]	—	≥2.8 [b]	—
Resistance to liquid penetration	cm H_2O	≥100	≥10	≥20	≥10
Tensile strength－Dry	N	≥20	≥20	≥20	≥20
Tensile strength－Wet	N	≥20	—	≥20	—
Bursting strength－Dry	kPa	≥40	≥40	≥40	≥40
Bursting strength－Wet	kPa	≥40	—	≥40	—

Note a：For the purpose of this standard Log_{10}CFU≤2 means maximum 300 CFU。

b：BI = 6.0 for the purpose of this standard means: no penetration, BI = 6.0 is the maximum achievable.

4. Test items

(1) Resistance to microbial penetration－dry
(2) Resistance to microbial penetration－wet
(3) Resistance to liquid penetration
(4) Tensile strength－dry and wet
(5) Bursting strength－dry and wet

5.Test method（Summary）：

5.1 Resistance to microbial penetration－dry

5.1.1 Apparatus and materials

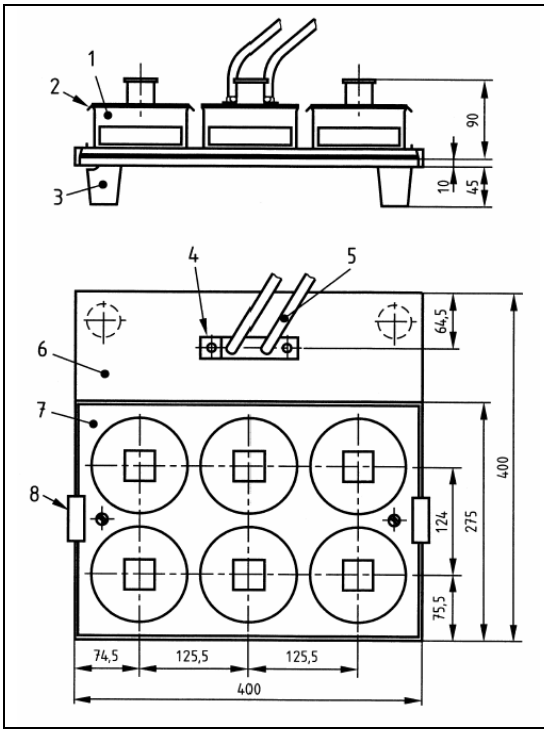
(1) tester of dry microbial penetration （see Figure 1）

(a) marble stone plate: size of 40 cm×40 cm, 10 mm thick, underneath which 4rubber stoppers are mounted at the corners.

(b) pneumatic ball vibrator, able to generate 20800 vibration per minute with a force of 650 N.
e.g. K13, made by ERKALAITE OY, Helsinki, Finland.

(c) compressed air flow meter : measure (158±1.58) L/min，the flow of the compressed air governs the vibration frequency.

(d) stainless steel plate : with 6 retaining holes of suitable dimensions to fit the containers, the plate being held to the stone plate by means of clips.

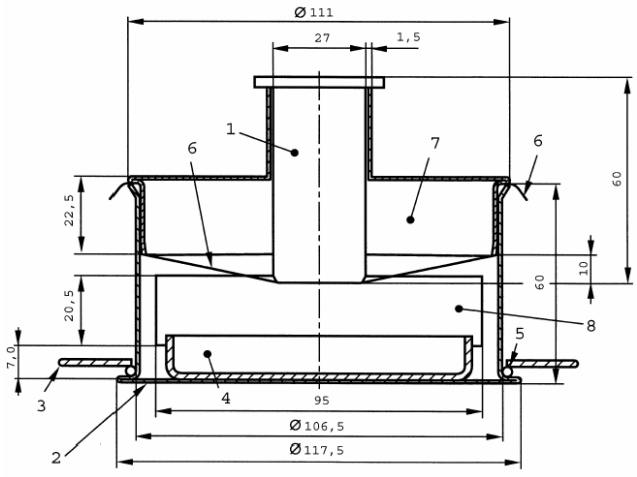


unit: mm

1. test container
2. test material
3. robber stoppers
4. pneumatic ball vibrator
5. pneumatic hoses
6. marble plate
7. fixing plate
8. clips

Figure 1 tester of dry microbial penetration

(e) Six stainless steel test containers : with a lid. The lid has a central aperture through which a metal plunger may be inserted to reach 10 mm under the lid to ensure that the test material is slack when inserted. Each container has a sedimentation plate insertion slot near the base. To ensure good contact between the containers and the stone plate by means of the fixing plate, each container is equipped with a rubber ring resting on its flanged base. The rim of the container is chamfered to prevent damage to the test piece when inserted.（see Figure 2）。



unit: mm

1. metal plunger
2. base of container
3. fixing plate
4. sedimentation plate
5. rubber ring
6. test material
7. lid
8. sedimentation plate insertion slot

Figure 2：test container

(2) sedimentation plate：a supply of 9 cm diameter Petri dishes containing TGE agar.
Annex：the ingredients of TGE agar including: Beef extract 3 g, Tryptone 5 g, Dextrose(glucose) 1 g, Agar 15 g, Distilled water 1000 mL。

(3) talc: 95%＜15 μm 。

(4) purified spores of *Bacillus subtilis* ATCC 9372 in a concentration of $\geqq 10^9$ /mL of ethyl alcohol commercially available.
(5) timer

5.1.2 Sampling and Preparation

(1) Preparation for contaminated talc
(a) Prepare 50 g sterile talcum powder and sterilize at 160 ℃ with dry heat for 2 to 3h for heating in a suitable container.
(b) Open the ampoule of 5 m; of the ethanolic spore solution. Spread the spore solution in 50 steps（50×100 μl） over the talcum powder.（After every step shake the closed vessel with a vortex vibrator.）。
(c) Put the opened vessel in a desiccator with silica gel and dry it at room temperature for 2 days to 3 days.（Weight the vessel before and after drying to assure complete drying）
(d) Estimate the bioburden expressed as cfu/g of the spore talcum mixture on TGE agar after incubation overnight at 35 ℃. The final concentration should be 10^8 CFU/g talc and it's necessary to ensure that the spores are homogeneously distributed in the talc.
(2) sampling：12 test pieces of 200 mm×200 mm.

5.1.3 testing procedure:

(1) Put test pieces in sterilizing bags and sterilize by the method given by the manufacturer.
(2) Put the containers in sterilizing bags and sterilize.
(3) Fix the bases of the containers onto the stone plate by means of the fixing plate and secure with the clips.
(4) Aseptically remove the pieces of test material from the bags and place over the mouths of the test containers. With the plungers distended downwards, affix the lids to the containers thus fixing the test pieces with controlled slackness. Then remove the plungers.
(5) A lidless sedimentation plate is inserted through the slot at base of each container, the seal the slot with adhesive tape.
(6) Put a 0.5 g portion of contaminated talc through the plunger orifice on to 5 of the test materials leaving the 6th one uncontaminated as a control（without talc）.
(7) Seal the orifices with cling film, and put a small plastic bag over each container.
(8) Turn the vibrator at an air flow of 158 L/min for 30min.
(9) Remove the plastic bag and adhesive tape. Insert the lids of the sedimentation plates through the slots, then remove sedimentation plates and incubate at 35 ℃ for 24 h.
(10) Count the number of colonies produced. The control plate should read 0. If not, the test should be aborted as there is extraneous contamination.
(11) Repeat the above steps, and test another 6 test pieces.

5.1.4 result and recording：

(1) Calculate the mean for the 10 valid results, and express as Log_{10}(CFU).

5.2 Resistance to microbial penetration－wet

5.2.1 Apparatus and materials

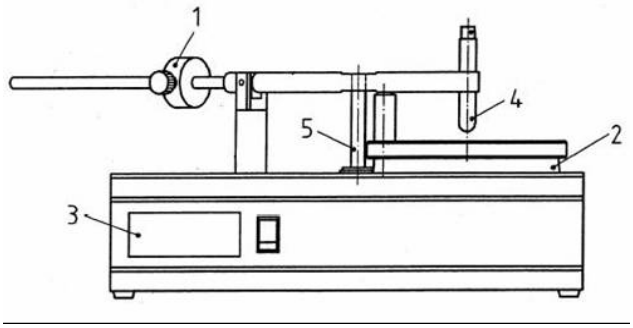
(1) wet microbial penetration tester：The apparatus has an electrically driven, timer-controlled turntable which holds a 14 cm diameter agar plate with 60 rpm. The finger with a semi-spherical, polished end, radius 11 mm, and the force from the finger on

the agar plate is (3±0.02) N. The finger is at the end of a horizontal lever, and the level is guided by an eccentric cam rotating at 5.60 rpm. The (see Figure 3)(2) carrier material－the material shall be wettable, solvent cast polyurethane(PU) polymer film of 30 μm thickness having elongation in the machine direction (350±50)%, and cross direction (400±75)%. Cut pieces of carrier material 25 cm×25 cm. Put it in a paper sterilizing bag, and sterilize by steam at 121℃

(3) high density polyethylene（HDPE）film：25 cm×25 cm, of approximate thickness 10 μm. The HDPE shall have a density of (950±2) kg/m^3 and a MFR（Melt Flow Rate, 190℃, 5 kg）of 0.27 g/10 min。

(4) *Staphylococcus aureus* ATCC 29213

(5) reference material：135 g/m^2 microfilament polyester fabric washed three times according to ISO 15797. The outcome of the test with reference material shall be in the range 0.70 ~ 0.96 expressed as CUM5.



1. counterweight
2. turntable
3. electronic timer
4. finger
5. eccentric

Figure 3：wet microbial penetration tester

5.2.2 Sampling and Preparation

(1) preparation of donor: culture *Staphylococcus aureus* ATCC 29213 for 18 to 24hr at (36±1)℃ on tryptic soy agar. Suspend 2 or 3 colonies in 3 ml tryptic soy broth. Incubate at (36±1)℃ for 18 to 24hr. Dilute with peptone water, in 1 : 10 steps to yield a concentration of 1×10^4~4×10^4 CFU/mL.

Open the sterilizer bag and extract the PU film still on ita paper carrier. Place the pieces of carrier material on a clean tinfoil, PU side up. Mark an area corresponding to the lid of the agar plate on the carrier. Distribute 1.0 mL of *Staphylococcus aureus* suspension over this area of the carrier. (using a disinfected glass spreader with L-shape to ensure an even distribution). Dry the donor at 56℃ for approx 30min. Using the donor the same day as it is prepared.

(2) sampling：5 pieces of 25 cm×25 cm or with a diameter of 25 cm.

5.2.3 Testing Procedure

(1) Place the plate 1 (with lid) on the rotateable disk.

(2) To standardize the material stretching force, use a circular weight consisting of an outer and an inner ring tighter weighing (800±1) g. First, put a test specimen on the ring, then put the donor , contaminated side down, on the specimen. Lastly cover the PU film with a piece of HDPE film, then push the outer ring down firmly.

(3) Place the ring with the material slightly slack on the first lidless agar plate with steel ring hanging freely outside the rotateable disk. Apply the finger to the HDPE film just inside the brim and in such a way that the test sample comes into contact with the agar surface. Start running the test for 15 min。

(4) Remove the last plate from the rotateable disk and closed with lid, and put a new agar plate on the rotateable disk with the retained ring assemblage.
(5) Perform the above-mentioned procedure (4) and use the other 4 plates（Xn）, total including 5 steps: 15 min（X1）, 30 min（X2）, 45 min（X3）, 1h（X4）and 1hour and 15min（X5）.
(6) Finally remove and discard the donor, turn the test specimen upside down, cover with the HDPE film and run the sixth plate for 15 min (Z), to complete the test run on the first replicate.
(7) Run the remaining 4 test specimen in the same procedure of (1) to (6).
(8) Incubate the agar plates with their lids in at (36±1) ℃ for 48h. If the liquid has accumulated on the agar surface, dry the plate(s) in a clean bench.
(9) Count the colonies of *Staphylococcus aureus on each plate expressed as* CFU, Disregard the count in the area with a radius of 15 mm around the centre of the plate.

5.2.4 Test Result and Record

(1) Calculate the BI (barrier index) value:

$T = Z + X1 + X2 + X3 + X4 + X5$

$CUM1 = X1/T$

$CUM2 = (X1 + X2)/T$

$CUM3 = (X1 + X2 + X3)/T$

$CUM4 = (X1 + X2 + X3 + X4)/T$

$CUM5 = (X1 + X2 + X3 + X4+ X5)/T$

$BI = 6 -$（CUM1 + CUM2 + CUM3 + CUM4 + CUM5）

(2) Calculate the mean for (BI) value of each test specimen, and the result expresses as the mean for (BI) value. In the report notes the concentration of *S. aureus* suspension.

5.3 Resistance to liquid penetration

5.3.1 Apparatus and materials

(1) liquid penetration tester：It should be possible to clamp the specimen horizontally and steadily. An area of the fabric of 100cm^2 is subjected increasing water pressure from below or from above the fabric. A manometer connected to the testing head should allow pressures to be read to an accuracy of 0.5cmH_2O. The sample does not slip in the clamps, and no leakage of water takes place at the clamps during the test period.
(2) The rate of increase of water pressure shall be（10±0.5）cm/min.
(3) The water in contact with the test specimen should be distilled or fully deionized water maintained at either 27±2℃ or 20±2℃.

5.3.2 Sampling and Preparation

(1) The standard temperate atmosphere for the testing has a relative humidity of (65±2) % at the temperature of (20±2) ℃.（The standard tropical atmosphere for testing has the same relative humidity and a temperature of (27±2) ℃.）
(2) sampling：Take five test specimens from different place in the sample (The sample may be tested without cutting specimens). Avoid folding the sample and the areas with deep crease or fold marks shall not be tested.
(3) The face (outer) of the sample will be in contact with the water.

5.3.3 Testing Procedure

(1) Wipe all water from the clamping surfaces. Clamp the conditioned specimen in the test head so that the face of the sample will be in contact with the water. The testing-side of sample will be the outer face or the face doesn't contact with human's skin.
(2) Subject the specimen immediately to increase water pressure, and be careful if the water is forced through the specimen prior to start of the test. Record the pressure as conventional centimeters of water, at which water first appears at the third place in the specimen.
(3) The accurancy for recording the pressure shall be the following :
   － until 1 mH_2O ：0.5 cm
   － more than 1 mH_2O and until 2 mH_2O：1 cm
   － more than 2 mH_2O ：2 cm

5.3.4 Test Result and Record

Calculate the mean of the pressure of each five specimen as cmH_2O.

5.4 Tensile Strength－Dry and Wet

5.4.1 **Apparatus and materials**

(1) tensile testing machine：Constant rate of extension type, equipped with an autographic recorder to register applied force and clamp separation.

5.4.2 Sampling and Preparation

(1) condition of the test pieces：The standard temperate atmosphere for the testing has a relative humidity of (65±2) % at the temperature of (20±2) ℃ at least 24 hours.
(2) Soaking treatment：The specimens for wet tensile test should be treated with soaking in stead of conditioning. Pick the specimens in to the container with distilled or fully deionized water at 20±2℃, let the specimen sinks in to the water at least 1 hour in the water. Then, removes a specimen form water, shake off excess water, and test immediately. If the sample is hard to be soaked completely, using the non-ionic wetting age diluted solution its concentration is below 0.1%. But before the testing, the specimen should be rinsed with water adequately. The specimens should be tested inside of 1 min after removing from water.
(3) sampling：The size of test pieces are （50±0.5）mm in wide. Cut ten test pieces in warp direction and ten in fill direction（five specimens for dry-testing and the other five specimens for wet-testing）.Ensuring they are all taken at least 100 mm from the edge of the sample.

5.4.3 Test Procedure

(1) The standard temperate atmosphere for testing has a relative humidity (R.H.) of （65±2）%at a temperature of（20±2）℃.
(2) Set the jaws of the tensile testing machine (200±1) mm apart. Clamp the test piece between them and straighten out the test piece. Apply a constant rate of extension of 100 mm/min, and start the machine until the specimen breaks.
(3) Record the force-elongation curve for each test piece. Use the force-elongation curve

to determine the maximum breaking strength in newtons(N). Record the results of the test in both the warp direction and fill direction.

5.4.4 Result and Record

(1) Determine the mean of the results in both the warp direction and fill direction. The value takes below the decimal first (the nearest 0.1N).

(2) The results should include dry tensile strength and wet tensile strength.

5.5 Bursting strength－Dry and Wet

5.5.1 Apparatus and materials

(1) bursting tester： the apparatus shall be capable of producing various constant rates of increase in volume per unit time between 100 cm^3/min and 500 cm^3/min to within ±10% of the indicated value, or the apparatus with a testing time to burst of （20±5）s may be applied. The clamping device shall provide for clamping the test specimen securely without distortion or damage and prevent slippage during the test. Height at burst up to 70 mm shall be indicated with an accuracy to ±1mm. A test area of 50 cm^2（79.8 mm diameter） shall be used. Other test areas of 100 cm^2（112.8 mm diameter）, 10 cm^2（35.7 mm diameter） or 7.3 cm^2（30.5 mm diameter） may be used by mutual agreement.

5.5.2 Sampling and Preparation

(1) atmospheres for condition : condition of the test pieces has a relative humidity of (65±2) % at the temperature of (20±2) ℃ at least 24 hours.

(2) According to the the test area of test machine, take 5 pieces of specimens to test.

(3) Soaking treatment : according to 5.4.2 (2)。

5.5.3 Testing Procedure

(1) Place the test specimen over the diaphragm so that it lies in a flat tensionless condition, avoiding distortion in its own place. Clamp it securely in the circular holder, avoiding jaw damage, to prevent slippage during the test.

(2) Adjust the distension recording device to the zero position.

(3) Set the constant rate of increase, and apply pressure to the test specimen until the fabric bursts. Measure the strength of rubber diaphragm to burst specimen and the strength of rubber diaphragm when clamp is removed.

(4) Calculate the bursting strength of each specimen by subtracting the strength of rubber diaphragm when clamp is removed from the strength of rubber diaphragm to burst specimen, and express as kPa（kilopascal）.

(5) Reject jaw breaks occurring within 2 mm of the clamping line.

5.5.4 Result and Record

(1) The test result express as the mean value of bursting pressure of the five specimens. If there are differences in the test results for both side of material, both sides should be tested and the results should be recorded.

(2) The results should include dry bursting strength and wet bursting strength.

6.Reference standard：

EN 13795-1 Surgical drapes, gowns and clean air suit, used as medical device, for patients, clinical staff and equipment-part 1: General requirements for manufacturers, processors and products

EN 13795-2 Surgical drapes, gowns and clean air suit, used as medical device, for patients, clinical staff and equipment-part 2: Test method

prEN 13795-3 Surgical drapes, gowns and clean air suit, used as medical device, for patients, clinical staff and equipment-part 3: Performance requirements and performance levels

prEN ISO 22610 Surgical drapes, gowns and clean air suit, used as medical device, for patients, clinical staff and equipment-Test method to determinate the resistance to wet bacterial penetration

EN ISO 22612 Clothing for protection against infectious agents-Test method for resistance to dry microbial penetration

EN 20811 Determination of resistance to water penetration-Hydrostatic pressure test

ISO 9073-3 Determination of tensile strength and elongation

ISO 13938-1 Bursting properties of fabrics-Part 1:Hydraulic method for determination of strength and bursting distension